

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/084,638
Filing Date: February 27, 2002
Appellants: Babich, Michael

Alice O. Martin
For Appellant

APPELLANT'S REPLY

This is a reply to the Examiner's Answer for the Appeal Brief filed 10/11/2007 appealing from the Office Action mailed 1/11/2006.

In reply to the Examiner's Answer mailed January 11, 2008, Appellant submits the following:

(9) Grounds for Rejection

Claims 17 and 22-28 were rejected under 35 U.S.C. §102 (b) as anticipated by U.S. Patent No. 5,583,046. (Valenta) The examiner added Vrtala et al. to Valenta.

The examiner admits that Valenta ('046) is silent as to whether the Bet v2 is multimeric. Bet v2 is only one species of profilin that only appears in Appellant's claim 27 as one of a laundry list of examples of monomers that can be formed into multimers. There are many other examples in claim 27. The examiner argues only that Vrtala teaches that Bet v2 naturally polymerizes in solutions. The examiner does not allege that Valenta ('046) or Vrtala teach any of these other monomers. Neither the Valenta ('046) patent nor Vrtala teach or suggest, nor does the examiner allege they teach or suggest, that multimeric profilin is an improvement in terms of diagnostic and therapeutic treatment of allergies.

Bet v2 is the only species of profilin in Valenta. It is only one form of profilin monomers, yet the examiner is extrapolating to all profilins forming multimers, arguing that it is inherent in profilin to form multimers.

The examiner argues that Vrtala is only used to illustrate "an already described process showing inherent properties of the molecule." (Examiner's Answer, page 3-4) This argument does not address that the claims on appeal are to a **method** of diagnosing and treating allergies with multimers. Claims are **not** directed to multimeric profilin per se. Even combining Valenta with Vrtala (which Appellant argues is inappropriate for the 102 rejection), there is no teaching or suggestion in the publication that a multimer would be the method of choice for diagnosis or therapy.

Publications cited by the examiner only refer to Bet v2, not to the general claims to profilin in the application under appeal nor to the numerous other examples presented in addition to Bet v2. Further, Valenta was satisfied with monomers used to administer to patients to

diagnostically determine allergenicity to the p14 allergen, the monomeric form of Bet v2 profilin.

In the Examiner's Answer, he relates about Valenta ('046):

The reference is silent as to whether the Bet v2 is multimeric.
and
Vrtala et al. teaches that Bet v2 naturally polymerizes in solution to form stable polymers.

Examiner's Answer, page 6.

In the Examiner's Answer the examiner reiterates that:

...applicant has not provided any objective evidence to support a difference between the prior art P14 allergen in the instant multimeric Bet v2. The record does not contain sufficient objective evidence that the referenced P14 allergen differs in any significant matter from that claimed multimeric Bet v2.

Examiner's Answer, page 7.

Appellant replies that it is not claiming the multimeric Bet v2, nor limiting methods of diagnoses and treatment to Bet v2. Vrtala has not proven that all profilin molecules, which have different sequences, different shapes, different molecular weights, different sizes, would first of all form multimers and polymers in solution, nor does the examiner equate the solution of Vrtala to that used in the present application. Moreover, the present application which the examiner refers to on page 10, lines 12-21 relates human profilin.

In response to the examiner's argument on page 8 citing *Atlas Powder Co.*, the present invention is not the discovery of a previously unappreciated property of a prior art composition, because claims are to methods of diagnoses and treatment, not to a composition or based on explaining a prior art function. There is nothing in the prior art that states that the function of a multimeric profilin is to give increased allergenicity. Neither does Appellant find in the references, nor has the examiner cited to the references, to say that they teach that a multimeric profilin has increased allergenicity. That is not an inherent property that could be appreciated by those of skill. The examiner has not refuted Appellant's argument:

It could be shown that recombinant Bet v2 formed polymers through disulfide bonds, and it is hence suggested that the **decreased allergenicity** of recombinant of rBet v2 might be related to its tendency to polymerize (*emphasis added*).

Examiner's Answer, pages 8-9.

This definitely shows that Vrtala teaches away from the present invention. The examiner has not convincingly refuted this point. The examiner negates, or argues against Appellant's contention that Vrtala teaches away from the instant claims, by saying Vrtala is an "evidentiary reference" and not part of the rejection. If Vrtala's comments are evidence to show knowledge of those skilled in the art, then the "teaching away" was also available to those of skill in the art reading Vrtala. The reference would not be likely to lead those of skill to conclude that they should then use multimeric profilin for allergenicity testing and treatment. Without Vrtala, Valenta cannot suffice to support a 102 rejection -- or even a 103, because the examiner admits not all claim elements are taught by Valenta. Even were it true that Bet v2 polymerizes in solution, that finding would never lead to any further development because it was a monomer in the '046 patent that Valenta thought they were giving to patients. No one else would have ever gone further with the concept of multimers based on Valenta. Also, even were Vrtala taken as teaching of a species of polymerization, a species does not anticipate a genus. In the present claims, Bet v4 is merely one of a multiple number of species of profilin in a dependent claim. Claims are to methods of using multimers of the genus.

Respectfully submitted,



Alice O. Martin
Reg. No. 35,601

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Barnes & Thornburg LLP
P. O. Box 2786
Chicago, IL 60690-2786